

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

**INFORMATION DISCLOSURE  
STATEMENT**

Docket Number:  
1662/61902

Application Number  
10/699,991

Filing Date  
November 3, 2003

Examiner  
To be Assigned

Art Unit  
1614

Invention Title  
PHARMACEUTICAL COMPOSITIONS AND DOSAGE  
FORMS FOR BUCCAL AND SUBLINGUAL  
DELIVERY OF TIZANIDINE AND METHODS OF  
ADMINISTERING TIZANIDINE SUBLINGUALLY OR  
BUCCALLY

Inventor(s)  
LERNER et al.

Address to:  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450 on:

Date: 01/21/04

Signature: Herpin G. Lerner

Sir:

1. In accordance with the duty of disclosure under 37 C.F.R. § 1.56 and in conformance with the procedures of 37 C.F.R. §§ 1.97 and 1.98 and M.P.E.P. § 609, attorneys for Applicants hereby bring the following references to the attention of the Examiner. These references are listed on the attached modified PTO Form No. 1449. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b).
2. Copies of patents, publications or other information listed on the modified PTO Form 1449 are enclosed.
3. It is believed that no fees are due in connection with this Information Disclosure Statement. However, should any fees be due, the Commissioner is authorized to charge Deposit Account No. 11-0600 for such fees. A duplicate copy of this communication is enclosed for charging purposes.

Dated: March 2, 2004

By: Paul Johnson  
Mary E. Werner Reg No. 30,333  
Paul Johnson (Reg. No. 35,559)

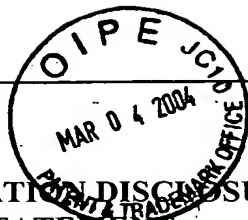
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**INFORMATIONAL DISCLOSURE  
STATEMENT  
BY APPLICANT  
PTO-1449**

ATTY. DOCKET NO.  
1662/61902

SERIAL NO.  
10/699,991

APPLICANT  
E. Itzhak LERNER et al.

FILING DATE  
November 3, 2003

GROUP

**U. S. PATENT DOCUMENTS**

EXAMINER INITIAL	PATENT NUMBER	PATENT DATE	NAME	CLASS	SUBCLASS	FILING DATE*

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 01/037808	November 22, 2000	WO				
	WO 01/028555	October 18, 2000	WO				

**OTHER DOCUMENTS**

EXAMINER INITIAL	AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
	<i>Physicians Desk Reference 55th ed. 670-673 (Medical Economics Co.: Montvale, N.J.2001).</i>
	Abbruzzese, G., "The Medical Management of Spasticity" <i>Eur. J. Neurol.</i> , <b>2002</b> , Suppl. 1,30-34, and 53-61.
	Kita, M. and Goodkin, D. E., "Drugs Used to Treat Spasticity" <i>Drugs</i> , <b>2000</b> , 59(3), 48795.
	Groves, L., et. al., " Tizanidine Treatment of Spasticity: A Meta Analysis of Controlled, Double-blind, Comparative Studies with Baclofen and Diazepam" <i>Adv. Ther.</i> , <b>1998</b> , 15(4), 241-51.
	Milanov, I., and Georgiev, D., "Mechanisms of Tizanidine Action on Spasticity" <i>Acta. Neurol. Scand.</i> , <b>1994</b> , 89(4), 274-79).
	Schapiro, R. T., "Management of Spasticity, Pain, And Paroxysmal Phenomena in Multiple Sclerosis" <i>Curr. Neurosci. Rep.</i> , <b>2001</b> , 1(3), 299- 302.
	Nance, P. W. , et. al. "Relationship of The Antispasticity Effect of Tizanidine to Plasma Concentration in Patients with Multiple Sclerosis" <i>Arch. Neurol.</i> , <b>1997</b> , 54(6), 731-36.
	Smith, C., et. al., "Tizanidine Treatment of Spasticity Caused by Multiple Sclerosis: Results of a Double-blind, Placebo Controlled Trial. US Tizanidine Study Group" <i>Neurology</i> , <b>1994</b> , 44(11 Suppl. 9), S34-43).
	Nance, P. W. et. al., "Efficacy And Safety of Tizanidine in The Treatment of Spasticity in Patients with Spinal Cord Injury. North American Tizanidine Study Group" <i>Neurology</i> , <b>1994</b> , 44(11 suppl. 9), S44 -52.

EXAMINER INITIAL		AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
		Burchiel, K. J. and Hsu, F. P., "Pain And Spasticity after Spinal Cord Injury: Mechanisms And Treatment" <i>Spine</i> , 2001, 26(24 suppl.) , S 146-60).
		Gelber, D. A. et. al., "Open-label Dose- titration Safety and Efficacy Study of Tizanidine Hydrochloride in The Treatment of Spasticity Associated with Chronic Stroke" <i>Stroke</i> , 2001, 32(8) 1841-6.
		Meythaler, J., M. et. al., "Prospective Assessment of Tizanidine for Spasticity Due to Acquired Brain Injury" <i>Arch. Phys. Med. Rehabil.</i> , 2001 , 82(9), 1159-63).
		Smith, T. R. , "Low-dose Tizanidine with Nonsteroidal Anti-inflammatory Drugs for Detoxification from Analgesic Rebound Headache, <i>Headache</i> , 2002, 42(3), 175-7.
		Saper, J. R. , et. al. , "An Open-label Dose-titration Study of The Efficacy And Tolerability of Tizanidine Hydrochloride Tablets in The Prophylaxis of Chronic Daily Headache, <i>Headache</i> , 2001, 41(4), 357-68.
		Murros, K., et. al., "Modified Release Formulation of Tizanidine in Chronic Tension-type Headache", <i>Headache</i> , 2000, 40(8), 633-7.
		D'Alessandro, R. , "Tizanidine for Chronic Cluster Headache" <i>Arch. Neurol.</i> , 1996, 53(11) 1093.
		Roberts, R. C. "Pharmacokinetics and Pharmacodynamics of Tizanidine" <i>Neurology</i> 1994, 44 (11 suppl 9), S29-31.
		de- Graff, E. M., et. al., "A Case of Tizanidine-induced Hepatic Injury, <i>J Hepatol.</i> , 1996, 25(5), 772-3.

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	